

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 540618101WO	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. PCT/US03/18657	International filing date (<i>day/month/year</i>) 13 June 2003 (13.06.2003)	(Earliest) Priority Date (<i>day/month/year</i>) 14 June 2002 (14.06.2002)
Applicant AMYLIN PHARMACEUTICALS, IN C		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the Report

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing:

☒ contained in the international application in written form.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. ☐ Certain claims were found unsearchable (See Box I).

3. ☒ Unity of invention is lacking (See Box II).

4. With regard to the title,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No. _____

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☒ None of the figures

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International application No.

JS03/18657

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claim Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claim Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1-4 and 19-22

Remark on Protest

☐
☐

The additional search fees were accompanied by the applicant's protest.
No protest accompanied the payment of additional search fees.

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International application No.

PCT/US03/18657

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61K 38/16; 31/00

US CL : 424/198.1; 514/1

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/198.1; 514/1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EAST, STN/BIOSIS, MEDLINE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	EL-SALHY et al, Peptide YY in gastrointestinal disorders. Peptides, Feb 2002, Vol. 23, pages 397-402, especially abstract, pages 398-399, and 401.	1-4 ----- 19-22
X --- Y	US 5,604,203 A (Balasubramaniam, A.) 18 February 1997 (18.02.1997), column 7.	1, 2, 4 ----- 3, 19-22
--- Y	DUMONT et al, Peptide YY derivatives as selective neuropeptide Y/peptide YY Y1 and Y2 agonists devoided of activity for the Y3 receptor sub-type. Brain Res. Mol. Brain Res. October 1994, Vol. 26, Issue 1-2, pages 320-324, especially abstract.	----- 19-22

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"B" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

29 February 2004 (29.02.2004)

Date of mailing of the international search report

22 APR 2004

Name and mailing address of the ISA/US

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BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

(i) The methods of Groups I-III are distinct methods, each having completely different method steps, using different compositions and having completely different outcomes; whereas Groups IV and V are drawn to two entirely different products, a composition comprising a PYY molecule or a PYY agonist and a probiotic bacterium, respectively.

(ii) The special technical features of Groups I-III are a method of treating a bowel condition comprising administering a pharmaceutically active formulation of PYY or a PYY agonist to a patient, a method of identifying a PYY agonist useful for the prevention or treatment of a bowel condition, and a method of identifying a PYY agonist useful for the prevention or treatment of a bowel condition, respectively, whereas the special technical features in Groups IV and V are a composition comprising a PYY molecule or an agonist of PYY molecule, and a probiotic bacterium comprising a nucleic acid encoding PYY or a PYY agonist, respectively. Since none of the special technical features of the Groups I-V is found in more than one of the inventions, unity of invention is lacking.

Accordingly, Groups I-V are not so linked by the same or a corresponding special technical feature as to form a single general concept.

2. In the absence of any response from the Applicant, this Authority will establish the International Preliminary Search Report based on the main invention. The claims drawn to the main invention are as follows:

Claims 1-4 and 19-22.

I. Claims 1-4, and 19-22, drawn to a method of treating a bowel condition comprising administering a pharmaceutically active formulation of PYY or a PYY agonist to a patient.

II. Claims 5-8, 23, and 24, drawn to a method of manufacturing a drug product comprising PYY or an agonist of PYY.

III. Claims 9 and 10, drawn to a method of identifying a PYY agonist useful for the prevention or treatment of a bowel condition.

IV. Claims 11-13, 16-18, and 25, drawn to a composition comprising a PYY molecule or an agonist of PYY molecule.

V. Claims 14 and 15, drawn to a probiotic bacterium comprising a nucleic acid encoding PYY or a PYY agonist.

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